IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

(1) JOHN HARRINGTON, individually,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**CIV-07-25-R**
	)	
(1) BIOMET INC., a foreign corp., and	)	
(2) ABC Corp., a domestic corp., and	)	
(3) XYZ Corp., a foreign corp., and	)	
(4) TERRY DOE, individually,	)	
	)	
Defendants.	)	

ORDER

Before the Court is the motion of Defendant Biomet, Inc., for summary judgment on Plaintiff's complaint. Doc. No. 25. Defendant asserts that Plaintiff has no legally sufficient evidence to support a products liability claim against Biomet; that Biomet had no duty to warn the Plaintiff of possible complications or risks associated with its prosthetic hip under the learned intermediary doctrine; that Plaintiff cannot present any evidence that the Biomet hip was negligently manufactured or designed; and that Plaintiff cannot support a claim for breach of warranty against it because he cannot identify any express or implied warranty made by Biomet on which he relied prior to undergoing total hip arthroplasty or any breach of a warranty, assuming its existence, and any claim for breach of warranty fails for lack of privity. Additionally, Defendant asserts that Plaintiff is not entitled to punitive damages because he cannot show fraud, malice, oppression, gross negligence or wanton or reckless disregard of the rights of others on Defendant's part.

Plaintiff in response and in opposition to Defendant's motion asserts that a Defendant cannot obtain summary judgment by daring a plaintiff to "prove it" or by showing the likelihood that a Plaintiff will be unable at trial to present evidence of the essential elements of his claims, citing and quoting *Northrip v. Montgomery Ward*, 529 P.2d 489 (Okla. 1974) and *Holland v. Urban Contractors, Inc.*, 131 P.3d 139 (Okla. Civ. App. 2005), *cert. denied* (Okla. 2006). Plaintiff further asserts that ample circumstantial evidence exists that there was a defect in the Biomet hip components. Specifically, Plaintiff points to what he maintains is evidence that the hip dislocated easily in Dr. Tompkin's surgical suite and while Plaintiff was in recovery, citing Plaintiff's medical records (Exhibit "4" to Plaintiff's Response). Plaintiff also asserts that there is no evidence that the Biomet components in question were specifically tested or any evidence that "goes beyond Plaintiffs [sic] foreseeable and expected conduct, and most importantly there is no mention of the spontaneous dislocation of the Biomet product." Response Brief at p. 5. Plaintiff claims his "medical records, testimony and an elimination of causes create a question of fact." *Id.* Plaintiff further argues that his own conduct is not a factor in a products liability claim because only unforeseeable abnormal use or misuse of a product precludes recovery and Plaintiff's conduct was within the range of conduct allowed by Biomet's own literature. Any limiting instructions, Plaintiff states, were to prevent pain and aid in recovery, not to prevent repeated dislocations. Plaintiff further asserts that assumption of risk is not a valid defense because Defendant must prove that Plaintiff had subjective awareness of a defect in the product and the consequences that would occur as a result of the defect. Thus, Plaintiff states that Defendant has the burden of

presenting evidence that Plaintiff knew the implant would dislocate repeatedly and has failed to present any such evidence.

Plaintiff further asserts that his failure to warn claim cannot be dismissed because Defendant gave no warning to either Dr. Puckett or the Plaintiff that the prosthetic hip would dislocate repeatedly, over eleven (11) times in a short period, under normal conditions or that this type of risk was associated with the Biomet hip. Plaintiff also asserts that the learned intermediary doctrine does not apply because a representative of Defendant Biomet was present during the operation and had an opportunity to visit Plaintiff and warn either the doctor or the Plaintiff of "the hidden dangers of the Defendant's implants." Response Brief at p. 8. The fact that Defendant's warnings were approved by the FDA does not preclude liability for failure to warn, Plaintiff asserts, because FDA labeling requirements are minimum requirements, Plaintiff states, citing *Edwards v. Basel Pharmaceuticals*, 933 P.2d 298 (Okla. 1997).

Plaintiff asserts that Defendant breached a warranty of merchantability because Defendant's prosthetic hip was not fit for its ordinary purpose of keeping the leg in place and rotating it. Likewise, the fact that Defendant's prosthetic hip dislocated many times proves that Defendant failed to exercise ordinary care, Plaintiff asserts. Plaintiff asserts that Defendant did not use the proper standard of care when advising the physician as to what type of prosthesis to implant in the Plaintiff, even though Plaintiff has failed to produce any evidence indicating that any representatives of Defendant advised Dr. Puckett as to what type or size of implant or component parts to use.

With respect to his claim for punitive damages, Plaintiff states that he "anticipates at the time of trial that he will present evidence that Biomet knew of such dislocations, advised their representatives to never suggest proper components to physicians, and knew of ongoing performance defects in the subject component design," Response Brief at p. 11, and that Plaintiff must be allowed to present such evidence.

First, Plaintiff apparently does not understand that federal procedure and federal case law relating to that procedure govern motions for summary judgment in federal court. The United States Supreme Court in *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 106 S. Ct. 2548, 91 L.Ed.2d 265, 274 (1986) made it perfectly clear that a party moving for summary judgment on an issue or issues on which the nonmoving party bears the burden of proof at trial need not present any evidence but needs only to point out the absence of evidence on that issue(s). If the nonmovant then fails to present evidence on such issue or issues, on which he or she will have the burden of proof at trial, the movant is entitled to summary judgment. *Id.*

Plaintiff has presented no expert testimony or other direct evidence of the existence of a defect in either the manufacture or the design of the Biomet prosthetic hip. Rather, Plaintiff relies exclusively on what he calls circumstantial evidence of a defect, which he does not specify was in design or manufacture, or just what the defect was. This circumstantial evidence consists entirely of the fact that Plaintiff had eleven dislocations of the Biomet prosthetic hip and the operative note of Dr. John T. Tompkins at the time he performed a revision of Plaintiff's hip arthroplasty, on February 11, 2005, that in flexion to

approximately 80 or 90 degrees with moderate adduction and 30 degrees of internal rotation the Biomet prosthetic hip that had been implanted in May of 2004 by Dr. Timothy Puckett "would easily dislocate with axial loading." Operative Note of John F. Tompkins, II, M.D., part of Exhibit "4" to Plaintiff's Response Brief at p. 2.

It is true that the Oklahoma Supreme Court has said that "circumstantial evidence may be used to support the probability of a defect, and that 'it is not necessary that such proof rise to such degree of certainty as to support only one reasonable conclusion and exclude all others.'" *Dutch v. Sea Ray Boats, Inc.*, 845 P.2d 187, 191 (Okla. 1992), citing *Kirland v. General Motors Corp.*, 521 P.2d 1353, 1364 (Okla. 1974) (quoting *Chickasaw Cotton Oil Co. v. Hancock*, 306 P.2d 330, (Okla. 1957). It is noted, however, that the Oklahoma Supreme Court said this in a case in which the product itself, a motor boat, was destroyed. *See Dutch v. Sea Ray Boats, Inc.*, 845 P.2d 187. The Tenth Circuit has recognized that a products liability plaintiff may prove his own case without identifying the particular defect operative with circumstantial evidence where the allegedly defective product has destroyed itself:

> Where as here, an allegedly defective product has largely destroyed itself, making direct evidence of the precise operative defect unavailable, the plaintiff may prove her case with circumstantial evidence, typically including expert testimony, even though she "is unable to point an accusing finger at a particular defective component. *Tiger [v. Admiral Corp.*, 612 P.2d 1381, 1383 (Okla. Civ. App. 1979), as modified on denial of cert. (May 23, 1980)]; *see Barber v. General Electric Co.*, 648 F.2d 1272, 1277-78 (10th Cir. 1981) (following *Tiger).*

Henderson v. Sunbeam Corp., 46 F.3d 1151, 1995 WL 39022 (10th Cir. Feb 1, 1995) (No.

93-6391).

Neither the Oklahoma Supreme Court nor the Tenth Circuit has said, however, that only in a case where the product is destroyed does the Plaintiff not have to identify what the defect is and that only in such a case may he or she rely on circumstantial evidence alone to prove that the product is defective. Accordingly, with some uncertainty, the Court will assume that the Plaintiff herein can prove the existence of a defect without identifying what the defect is and exclusively by circumstantial evidence, even though the product - the prosthetic hip - was not destroyed and/or there are numerous prosthetic hips of the same type and size available. However, the Court observes that there is obvious tension between the principle that a plaintiff may prove the existence of a defect, without identifying it, by circumstantial evidence and the principle recognized by the Oklahoma Supreme Court in *Kirkland* and its progeny, adhered to by the Tenth Circuit, that "we do not infer that the injury is itself proof of the defect, or that proof of injury shifts the burden to the defendant." *Kirkland v. General Motors Corp.*, 521 P.2d at 1363. *See, e.g., Bruce v. Martin-Marietta Corp.*, 544 F.2d 442, 448 (10th Cir. 1976) ("Proof of injuries in an air crash does not prove defective design and raises no presumption of defectiveness."). This is particularly the case here where Plaintiff is relying solely on the fact that his Biomet prosthetic hip dislocated eleven times and an operative note that the hip dislocated easily during manipulation with certain degrees of flexion adduction and internal rotation with axial loading at the time of revision surgery in February 2005 to prove that the prosthetic hip was defective in some manner, i.e., to raise an inference that the prosthetic hip and/or component thereof was

defective in some unspecified manner. Moreover, in this case, Plaintiff is apparently relying on this same circumstantial evidence to raise an inference that the prosthetic hip was unreasonably unsafe, beyond that which would be contemplated by an ordinary consumer having ordinary knowledge common to the community as to its characteristics, and that a defect in the prosthetic hip caused Plaintiff's injuries, i.e., the dislocations and the sequelae thereof. In this case, then, Plaintiff's evidence of three of the essential elements of a manufacturer's products liability claim is the same circumstantial evidence – that Plaintiff had eleven hip dislocations and an operative note during revision surgery (which Plaintiff does not analyze). This seems to the Court to be tantamount to saying that the mere fact that the hip dislocated eleven times proves or raises a presumption that the prosthetic hip was defective, unreasonably unsafe and was the cause of the Plaintiff's injuries, i.e., the dislocations!

Nevertheless, the Court will assume, for purposes of Defendant's motion for summary judgment that the fact that Plaintiff's Biomet hip dislocated eleven times is sufficient to raise an inference that the prosthetic hip was defective in design or manufacture. But in light of other evidence in the record before the Court, that evidence is insufficient to support the probability of a defect or anything more than a mere possibility of the existence of a defect, and that the defect caused Plaintiff's injuries, i.e., the dislocations and sequelae thereof. This evidence includes evidence that hip dislocation after implantation of a prosthetic hip is common to all prosthetic hips, not just the Biomet hip, Deposition of Timothy Puckett, M.D. (Exhibit "D" to Defendant's Brief) at p. 13, and is the most common problem that occurs

with hip replacements. *Id.* at p. 9; Affidavit of Dr. Charles Robert Steves (Exhibit "E" to Defendant's Brief) at p. 7. This evidence also includes evidence that before his first hip dislocation, Plaintiff fell and injured the ligaments which hold the prosthetic hip in place. *See* Deposition of Plaintiff (Exhibit "B" to Defendant's Brief) at p. 44; Deposition of Timothy Puckett, M.D., (Exhibit "D" to Defendant's Brief at p. 23; Progress Note dated July 14, 2004 (part of Exhibit "K" to Defendant's Brief) at 000068 ("possible avulsion of external rotators"); Affidavit of Dr. Charles Robert Steves (Exhibit "E" to Defendant's Brief) at p. 6. It also includes evidence that three days after Plaintiff reported his fall, Plaintiff suffered his first hip dislocation which resulted in additional damage to his ligaments and fibrous tissue surrounding the prosthetic hip, which hold the prosthetic hip in place. Specifically, the Plaintiff tore and stretched these ligaments. *See* Puckett Deposition at p. 27; Steves Affidavit at ¶¶ 7 and 8; Progress Note dated July 17, 2004. Moreover, there is evidence that trauma due to dislocation causes more laxity in the fibrous tissues making the prosthetic joint less stable and susceptible to further dislocations, *ee* Steves Affidavit at ¶ 8; Deposition of Phillip Martin Gibbs (Exhibit "H" to Defendant's Brief) at pp. 120-21, and that Plaintiff was advised that he was "more subject to" additional dislocations as a result of the first dislocation. Plaintiff's Deposition at p. 51.

Dr. Tompkins' statement in his Operative Note dated February 11, 2005, when Dr. Tompkins performed revision of Plaintiff's hip replacement surgery, that the hip "would easily dislocate" does not have the significance Plaintiff would like to attach to it and does not raise an inference that the original Biomet hip was defective for a number of reasons.

First, by the time of this revision surgery, Plaintiff had already had at least eleven (11) hip dislocations, which, it is undisputed, had damaged and loosened the ligaments and fibrous tissue around the prosthesis, making it more subject to dislocation than when it had been implanted in May of 2004. Indeed, Dr. Tompkins noted that "[t]here was some fibrous tissue extending from the posterior aspect of the acetabulum laterally but no tissue extending from the posterior acetabulum to the proximal femur." Operative Notes at p. 2(emphasis added). Moreover, Dr. Tompkins was manually manipulating the hip joint in surgery and its easy dislocation was noted only during flexion to 80 to 90 degrees with moderate adduction, 30 degrees of internal rotation (such rotation Plaintiff was warned not to do, i.e., not to turn his foot inward) and axial loading. Plaintiff has not presented any evidence that such movement and loading is common in ordinary movement of the hip and leg and/or that such movements were not movements Plaintiff was warned not to engage in to prevent dislocation. Finally, Dr. Tompkins' operative notes reveals that Dr. Tompkins decided, after "experimenting during surgery using trial heads with differing neck lengths, to use a prosthetic head that had 12 mm additional neck length" which was stable at greater degrees of flexion, adduction and internal rotation, to achieve maximum stability. *See Id.* at pp. 2-3. This evidence suggests that either Dr. Puckett chose a head with insufficient neck length for stability and to prevent dislocation for the initial hip replacement or that the longer neck length was necessary at revision surgery to achieve stability and minimize the risk of dislocation because of injuries to and laxity of Plaintiff's fibrous tissue surrounding his joint as a result of Plaintiff's fall and his numerous dislocations.

In the face of this evidence, Plaintiff's circumstantial evidence does not support an inference that a defect in the Biomet prosthetic hip was probable. At most, the fact that Plaintiff had eleven dislocations suggests that it is possible that a defect in the Biomet prosthetic hip existed and caused the dislocations, i.e., the Plaintiff's injuries. This is insufficient to meet Plaintiff's burden on issue of defect on which he has the burden of proof. *See Dutch v. Sea Ray Boats, Inc.*, 845 P.2d at 190-91 (a plaintiff may use circumstantial evidence to satisfy his or her burden of showing the existence of a defect that such evidence must support the probability of a defect; showing the mere possibility that a defect caused the injury is insufficient).

As to the existence of a manufacturing, as opposed to a design, defect, Defendant Biomet prepared a Medical Device Report pursuant to Food and Drug Administration requirements and guidelines after receiving notice of Plaintiff's complaint via his lawsuit and conducted an investigation to determine whether there were any problems or non-conforming reports issued during the manufacturing of the device in question. Medical Device Report (Exhibit "N" to Defendant's Brief); Deposition of Rex White (Exhibit "G") to Defendant's Brief) at pp. 38-39. Biomet found no evidence of any issues of non-conformance with product specifications during the manufacturing process. Medical Device Report; White Deposition at pp. 40-42.

Additionally, with respect to the issue of a defect, whether of manufacturing or design, there is substantial evidence in the record that there was no failure of the Biomet hip or any of its component parts; that it functioned properly and worked as it was intended; and that

it did not cause or contribute to Plaintiff's dislocations. Deposition of Timothy Puckett (Exhibit "D" to Defendant's Brief) at pp. 15, 27, 28, 31-34, 38-39, 40-41 and 42; Steves Affidavit (Exhibit "E" to Defendant's Brief) at ¶ 13. There is also substantial evidence in the record that tearing, stretching and/or loosening of the ligaments and fibrous tissue surrounding Plaintiff's prosthetic hip, which ligaments and tissue act to restring the hip, hold it in place and create stability, resulting from Plaintiff's overexertion, failure to follow instructions on avoidance of excessive flexion, adduction and internal rotation, Plaintiff's fall and/or Plaintiff's first dislocation were the cause of Plaintiff's multiple dislocations. Puckett Deposition at 18-19, 20, 21-23, 26-27, 28, 30, 34, 37, 38; Steves Affidavit at ¶¶ 6, 7, 8, 10 and 12. *See also* Deposition of Plaintiff (Exhibit "B" to Defendant's Brief) at p. 51; Progress Notes dated June 16, 2004; July 14, 2004; July 17, 2004; July 28, 2004 (part of Exhibit "K" to Defendant's Brief; and Operative Note of John F. Tompkins II, M.D. (Part of Exhibit "4" to Plaintiff's Response) at pp. 2 and 3 (no fibrous tissue extending from the posterior acetabulum to the proximal femur; prosterior capsule reconstructed).

With respect to his claim for failure to warn, Plaintiff states as follows:

> In the case at hand, the Defendant gave no warning that stated an internal devise would dislocate repeatedly over eleven (11) times in a short amount of time under normal conditions or that this type of risk is associated in the product. The Defendant did not provide Dr. Puckett or the Plaintiff with the proper warnings that would identify the risks other than a broad encompassing list of possibilities. *See package insert labled as Exhibit 6).* Furthermore, a representative of the Defendant Biomet was present during the operation and had an opportunity to visit the patient and warn either the doctor or the patient of the hidden dangers of the Defendant's implant. *(See Vickers Deposition, 14-17 attached Exhibit 2).* For that reason, a bar by the learned intermediary doctrine does not apply since Defendant's gave no warnings to

> Dr. Puckett of the possible presence a damaged acetabular cup or warnings that low impact activities would result in repeating dislocations. Dr. Puckett succinctly states: "I mean, I've had people dislocate two or three times, but not this many times." *(See Puckett Deposition P. 52 L.17-19 attached as Exhibit 1).*
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> Therefore, the most likely scenario to be set before a jury is that the Defendants had not even considered such a problem and did not consider warning of the possibility of spontaneous dislocation. *(See Medical Report dated February 11, 2005 attached Exhibit 4).*
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> In addition, FDA Requirements of labeling are minimum requirements, not reach a minimum standard of care. The Oklahoma Supreme Court has stated:
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> > It may be that in certain instances compliance with FDA warning procedures will satisfy all state law requirements but although compliance with FDA standards may prove an effective starting ground it is not necessarily conclusive.
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> *Edwards v. Basel Pharmaceuticals*, 933 P.2d 298 (Okla. 1997). Accordingly, Defendant cannot claim that since the label met FDA requirements, liability was extinguished. If a defect existed that caused the repeated dislocations, the Defendant did not properly warn of it. . . .
>
> Plaintiff's Response at pp. 7-8.

However, it is undisputed that Defendant provided a warning to Dr. Puckett, who implanted the Biomet prosthetic hip in the Plaintiff, by providing a package insert with each component part of the prosthetic hip, stating that "[f]ailure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure" and that "[t]he patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred." Exhibit "F" to Defendant's Brief. In the warning to operating

surgeon, the package inserts also state that "[e]xcessive activity, trauma and weight gain have been implicated with premature failure of the implant by loosening fracture and or wear." *Id.* Finally the package inserts all clearly list as a possible adverse effect "[d]islocation and subluxation due to inadequate fixation and positioning" and that "[m]uscle and fibrous tissue laxity can also contribute to these conditions." These warnings to the operating surgeon as to the risk of dislocation were adequate as a matter of law. *See Cox v. Murray Ohio Manufacturing*, 732 F. Supp. 1555, 1562 (W.D. Okla. 1987); *Steele v. Daisy Manufacturing Co.*, 743 P.2d 1107, 1109 (Okla. Civ. App. 1987) (adequacy of warnings may be resolved summarily as a matter of law). Because Defendant's warnings to the operating surgeon were adequate, Defendant cannot be liable to Plaintiff, the ultimate consumer, pursuant to the "learned intermediary doctrine." *See Edwards v. Basel Pharmaceuticals*, 933 P.2d 298 (Okla. 1997); *Tansy v. Dacomed Corp.*, 890 P.2d 881 (Okla. 1994); *McKee v. Moore*, 648 P.2d 21, 23-24 (Okla. 1982). However, even if Defendant's warning to the operating physician, Dr. Puckett, could be considered inadequate because it did not specifically warn of the risk of repeated dislocations, Defendant's failure did not cause Plaintiff's injuries because it is undisputed that Plaintiff was advised both before and after surgery and repeatedly thereafter of the risk of dislocation and what precautions to take and movements not to engage in to prevent or minimize the risk of dislocation, was instructed on an exercise regimen for strengthening the hip, was advised not to overdo use of the leg and that Plaintiff was advised after his first dislocation that because of it he was subject to additional dislocations. There is no evidence before the Court that the presence of a damaged

acetabular cup causes a dislocation or that that part of Plaintiff's prosthetic hip was damaged so Plaintiff's arguments of failure to specifically warn of dislocation due to a damaged acetabular cup are irrelevant. Likewise, there is no evidence before the Court that Plaintiff's dislocations were caused by "low impact activities." In any event, Defendant's warnings of dislocations and subluxation as possible adverse effects of implantation of the prosthetic hip components and that a patient's failure to follow postoperative care instructions could compromise the procedure's success were broad enough to cover the risk of dislocation for any reason. Defendant is entitled to summary judgment on Plaintiff's failure to warn claim.

In support of his negligence theory of liability, Plaintiff asserts that although a Biomet representative was in the surgery suite when the Biomet prosthetic hip was implanted in the Plaintiff, the representative did not advise Dr. Puckett as to what size and type of components to use and did not suggest to the surgeon that a different implant might be more appropriate for a younger individual such as the Plaintiff. *See* Plaintiff's Response at pp. 9-10. Plaintiff suggests that by failing to advise Plaintiff's surgeon as to what size and type of components to use Defendant failed to act with ordinary care. However, the evidence Plaintiff cites to support his assertion that Biomet's representative never advises a surgeon on what size and types of components to use does not support that assertion. In any event, however, Plaintiff fails to show either that Defendant had a duty to advise the surgeon and breached that duty or that Defendant voluntarily undertook to advise Dr. Puckett as to what size and types of components to use and that it breached that duty, much less that such negligence was the cause of Plaintiff's injuries. Accordingly, Defendant is entitled to summary judgment on

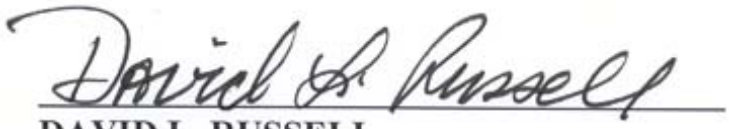
Plaintiff's negligence claim.

There is no evidence that Defendant made any express warranties to Plaintiff. Plaintiff suggest that Defendant breached the implied warranty of merchantability, Okla. Stat. tit. 12A, § 2-314, because its prosthetic hip or hip components were not fit for the ordinary purpose for which such goods are used. Assuming that Plaintiff as the ultimate purchaser can recover under this theory, that the prosthetic hip components are "goods" within the meaning of Okla. Stat. tit. 12A, § 2-105, and that a claim for breach of the implied warranty of merchantability is not preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (MDA), 21 U.S.C. § 360k(a), *see Oja v. Howmedica, Inc.*, 111 F.3d 782, 788-89 (10th Cir. 1997) (MDA did not preempt state law failure to warn claim), Defendant has presented a plethora of evidence showing that the prosthetic hip was fit for its ordinary purpose and Plaintiff has failed to present any evidence beyond the fact of the dislocations that it was not. It is undisputed that all prosthetic hips are subject to the risk of dislocation and that dislocation is the most common problem associated with a prosthetic hip. A prosthetic hip does not become unfit for its ordinary purpose merely because it presents a risk inherent in the nature of all goods of that type. Defendant is entitled to summary judgment on Plaintiff's claims for breach of express and/or implied warranties.

In accordance with the foregoing, Plaintiff's claim for punitive damages is moot and Defendant Biomet, Inc., is entitled to summary judgment on Plaintiff's complaint. The

motion of Defendant Biomet, Inc., for summary judgment on Plaintiff's complaint [Doc. No. 25] is GRANTED.

IT IS SO ORDERED this 3rd day of June, 2008.



DAVID L. RUSSELL
UNITED STATES DISTRICT JUDGE